

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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**In re US Pat. No.:** 7,297,688

**Issue Date:** November 20, 2007

**Inventors:** Gary S. GRUBB

**Group Art Unit:** 1617

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**Examiner:** San-ming Hui

**Serial No.:** 09/872,250

**Confirmation No.:** 4735

**Filed:** June 1, 2001

**Docket No.:** AM100058 (103250.10601)

**For: STARTER KIT FOR LOW DOSE ORAL CONTRACEPTIVES**

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VIA EFS WEB;

Date Sent: January 29, 2008

**ATTN: CERTIFICATE OF CORRECTION**

**BRANCH**

**Commissioner for Patents**

**P.O. BOX 1450**

**Washington, D.C. 20231**

**REQUEST FOR CERTIFICATE OF CORRECTION  
UNDER 37 C.F.R. § 1.322**

SIR:

Applicants hereby request correction of the above-referenced patent. Specifically, patent owner notes the following error(s):

In column 2, line 15, please correct “ethinylestradiol” to read “ethinyl estradiol”;

In column 3, in the 7<sup>th</sup> data line of the table for Example 1, “LNG 125mg 10 days” should read “LNG 125ug 10 days”;

In column 3, in the 7<sup>th</sup> data line of the table for Example 2, “LNG 125mg 10 days” should read “LNG 125ug 10 days”;

In column 5, in the 1<sup>st</sup> data line of the table for Example 10, “DSG 250ug 21 days 1” should read “DSG (desogestrol) 250ug 21 days 1”;

In column 5, in the 1<sup>st</sup> data line of the table for Example 11, “NGM 250ug 21 days 1” should read “NGM(norgestimate) 250ug 21 days 1”;

In claim 3, “multiple” should read “multiple”;

In claim 5, “ethinylestradiol” should read “ethinyl estradiol”.

An amendment correcting these errors is submitted herewith on the accompanying form PTO/SB/44, in duplicate.

With respect to the correction of “ethinylestradiol” to “ethinyl estradiol” Applicants respectfully submit that although they believe those of skill in the art would recognize the two terms to be identical, the latter is a preferred usage, and therefore, correction is requested.

With respect to the correction of the tables for Examples 1 and 2, Applicants respectfully assert that the correction from “125 mg” to “125 ug” merely corrects a typographical error. One skilled in the art, reviewing the contents of the table, and the surrounding specification, would recognize that that 125ug is in line with the other data, while 125mg is about a thousand fold increase

Applicants respectfully submit the prosecution history supports the requested corrections. At least one error appears to have been made by Applicant. Any such errors were made without deceptive intent. Since at least one error occurs in a claim, Applicants respectfully submit that issuance of a Certificate of Correction is warranted to assure proper interpretation of the claim.

The Commissioner is hereby authorized to debit deposit account no. 50-0436 for the fee due for issuing a Certificate of Correction as well as any fee due, since the error appears to have been made by applicant without deceptive intent.

Early action on this Request and issuance of a Certificate of Correction is respectfully requested.

Respectfully submitted,

Pepper Hamilton LLP

/Michael A. Patané/

by: Michael A. Patané

Reg. No. 42,982

Date: January 29, 2008

## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

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PATENT NO. : 7,297,688  
APPLICATION NO.: 09/872,250  
ISSUE DATE : November 20, 2007  
INVENTOR(S) : Gary S. GRUBB

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 2, please correct the paragraph spanning lines 14-15 as follows:

Suitable estrogens include 17 $\beta$ -estradiol, estrone, or a salt thereof, estriol, ~~ethinylestradiol~~ ethinyl estradiol and mestranol.

In column 3, please correct the Tables labeled Example 1 and Example 2 as follows:

EXAMPLE 1

Compound	Amount (dosage unit)	Duration	Cycle
LNG (levonorgestrel)	150 ug	21 days	1
EE (ethinyl estradiol)	30 ug		
LNG	50 ug	6 days	2
EE	30 ug		
LNG	75 ug	5 days	
EE	40 ug		
LNG	125 mg ug	10 days	
EE	30 ug		
LNG	100 ug	21 days	3
EE	20 ug		

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Pepper Hamilton LLP  
400 Berwyn Park, 899 Cassatt Road  
Berwyn, PA 19312

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

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It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

### EXAMPLE 2

Compound	Amount (dosage unit)	Duration	Cycle
LNG (levonorgestrel)	150 ug	21 days	1, 2
EE (ethinyl estradiol)	30 ug		
LNG	50 ug	6 days	3, 4
EE	30 ug		
LNG	75 ug	5 days	
EE	40 ug		
LNG	125 mg ug	10 days	
EE	30 ug		
LNG	100 ug	21 days	5
EE	20 ug		

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It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 5, please correct the tables labeled Example 10 and Example 11 as follows:

EXAMPLE 10

Compound	Amount (dosage unit)	Duration	Cycle
DSG ( <u>desogestrol</u> )	250 ug	21 days	1
EE	30 ug		
DSG	50 ug	7 days	2
EE	35 ug		
DSG	100ug	7 days	
EE	30 ug		
DSG	150 ug	7 days	
EE	30 ug		
DSG	150 ug	21 days	3
EE	20 ug		
EE	10 ug	5 days	

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It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

### EXAMPLE 11

Compound	Amount (dosage unit)	Duration	Cycle
NGM ( <u>norgestimate</u> )	250 ug	21 days	1
EE	30 ug		
NGM	180	7 days	2
EE	35 ug		
NGM	215 ug	7 days	
EE	35 ug		
NGM	250 ug	7 days	
EE	30 ug		
NGM	250 ug	21 days	3
EE	20 ug		

In claim 3, please amend the claim as follows:

3. The starter kit of claim 1 wherein ~~multiple~~ multiple cycle packs are packaged together as a single unit.

In claim 5, please amend the claims as follows:

5. The starter kit of claim 1 wherein the estrogen is ~~ethinylestradiol~~ ethinyl estradiol.

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